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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,959	02/12/2002	Avery J. Evans	SPEC-6150	6989

7590 06/29/2006

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EXAMINER
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RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/074,959

Applicant(s)

EVANS ET AL.

Examiner

Anu Ramana

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-9 and 17-19 is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-16, 21-27 and 29-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 16, 2006 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

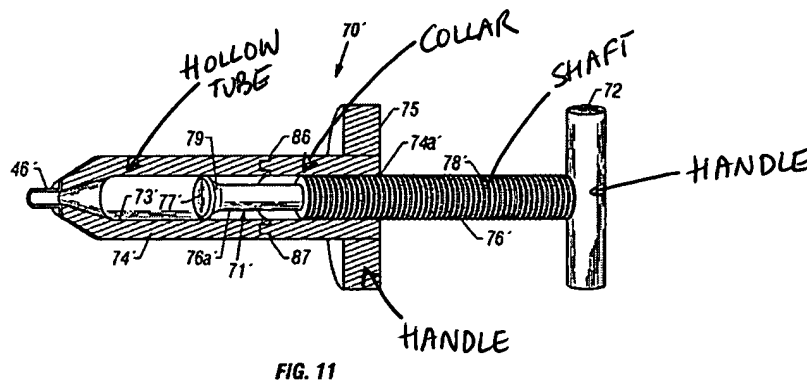
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 15-16, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Neiimeister et al. (US 4,560,352).

Neiimeister et al. disclose a dispenser assembly for dental compositions including: a plunger assembly having a shaft 46 with a threaded middle portion, a handle 51 attached to a first end of the shaft; a dispenser hub assembly including a collar 45 and a handle 61 attached to the collar; and a hollow tube or casing 4(Fig. 2, col. 3, lines 8-68, col. 4 and col. 5, lines 1-20).

Claims 1-2, 4-5, 10, 15-16, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Preissman (US 6,383,190).

Preissman discloses a system for delivery of bone cement including: a plunger assembly with a shaft 76' having a threaded middle section and a handle 72 attached to a first end of the shaft; a dispenser hub assembly having a collar with an internally threaded portion and a handle 75; a hollow tube 74' removably engaged with the dispenser hub assembly; and a sealing element such as an O-ring 77' mounted on the shaft (Figs. 10-12C, 18, col. 11, lines 62-67, col. 12, col. 13, lines 1-13, col. 14, lines 11-67). Also see marked up Figure 11 below.



Claims 1-2, 10, 15, 16, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Pierson et al. (US 6,571,992).

Pierson et al. disclose a syringe for dispensing pastes and putties, for e.g. dental restoratives, i.e., bone cement, including: a plunger having a shaft with a threaded middle portion, a handle 90 attached to a first end of shaft 70 and a piston or "unthreaded second end" 80; and a dispenser hub assembly wherein the hub assembly includes a collar 60 with a threaded portion 63 and a hand grip 51 attached to the collar (Figs. 1, 2 and 6, col. 2, lines 52-67, col. 3 and col. 4, lines 1-51).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12 and 31 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190).

Preissman discloses that a pressure applicator 50 is formed of clear nylon or other chemically compatible material and that the volume is preferably 10 cc and up to contain sufficient implant material (col. 10, lines 26-29 and col. 14, lines 58-64).

Regarding claim 11, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made applicator 70' with column 74' approximately 10 cc in volume, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 12 and 31, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed pressure applicator 70' of clear nylon since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein compatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 13 and 32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190) in view of LeVeen et al. (US 4,312,343).

Preissman discloses all elements of the claimed invention except for graduations on hollow tube 74'.

LeVeen et al. teach the barrel of a syringe being made of a transparent material and volume graduation markings on the barrel (col. 2, lines 29-38).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided volume graduation markings on the Preissman hollow tube to indicate the volume of material contained within.

Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Preissman (US 6,383,190) in view of Fischer (US 5,603,701).

Preissman discloses all elements of the claimed invention except for handle 92 being ergonomically shaped.

Fischer teaches knob 80 of a syringe apparatus to be shaped to facilitate ease of gripping and manipulation by the user with a minimal amount of wrist rotation (col. 5, lines 46-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an ergonomically shaped hand knob in the Preissman apparatus, as taught by Fischer for ease of manipulation by the user.

Claims 3-5 and 11 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992) in view of Preissman (US 6,383,190).

Pierson et al. disclose a sealing means such as a piston 80 that may be snap-fit or otherwise connected to plunger 70 (col. 4, lines 17-23).

Pierson et al. disclose the claimed invention except for: (1) a sealing means such as an O-ring disposed in a groove in plunger 70; (2) an enlarged funnel-shaped opening at a first end of the hollow tube; and (3) volume of the hollow tube is 10 cc.

Preissman teaches a sealing element such as an O-ring disposed on a plunger 55 (col. 9, lines 50-56). Preissman teaches an embodiment of an applicator to have an enlarged introduction section so that a plunger can be introduced into implant material in the applicator without forming a seal where compliant bubbles may be trapped (col. 16, lines 66-67 and col. 17, lines 1-65). Preissman also teaches an applicator volume of 10 cc and up to contain sufficient implant material (col. 10, lines 26-29 and col. 14, lines 58-64).

Regarding claims 4 and 5, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a sealing element such as an O-ring as, for example, taught by the Preissman reference for the piston of the Pierson et al. device wherein so doing would amount to mere substitution of one

functionally equivalent sealing means for another within the same art and the selection of any of these sealing means would work equally well in the claimed device.

Regarding claim 3, it would have also been obvious to one having ordinary skill in the art at the time the invention was made to have provided an enlarged introduction section in the Pierson et al. applicator, as taught by Preissman, so that a seal is not formed when a plunger is introduced into material in the applicator.

Regarding claim 11, Pierson et al. disclose the claimed invention except for the volume of barrel 20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made barrel 20 with a volume of 10 cc, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 12-13 and 31-32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992) in view of LeVeen et al. (US 4,312,343).

Pierson et al. disclose all elements of the claimed invention except for barrel 20 being made of a transparent material and graduations on barrel 20.

LeVeen et al. teach the barrel of a syringe being made of a transparent material and volume graduation markings on the barrel (col. 2, lines 29-38).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided volume graduation markings on the Pierson et al. barrel to indicate the volume of material contained within.

Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Pierson et al. (US 6,571,992) in view of Fischer (US 5,603,701).

Pierson et al. disclose all elements of the claimed invention except for handle 90 being ergonomically shaped.

Fischer teaches knob 80 of a syringe apparatus to be shaped to facilitate ease of gripping and manipulation by the user with a minimal amount of wrist rotation (col. 5, lines 46-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an ergonomically shaped hand knob in the Pierson et al. apparatus, as taught by Fischer for ease of manipulation by the user.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,395,007) in view of Preissman (US 6,383,190).

Bhatnagar et al. disclose a kit having a cement delivery means 42, a tubing assembly 44 removably attached to the cement delivery means 42, a cannula 12, a stylet 2, a hammer and a forceps (Fig. 4, col. 5, lines 31-66, col. 6, lines 1-35, col. 8, lines 45-59, col. 9, lines 46-67, col. 10, lines 1-26 and lines 55-61).

Bhatnagar et al. further disclose that any cement delivery means could be used (col. 9, lines 7-17).

Bhatnagar et al. disclose all elements of the claimed invention except for a cement delivery means including a plunger assembly and a dispenser hub assembly disposed around the shaft.

Preissman teaches a cement delivery means having a plunger assembly with a shaft and a handle attached to an end of the shaft and a dispenser hub assembly around the shaft (see previous discussion of Preissman).

It would have been obvious to one of ordinary skill in the art at the time the invention was made have substituted a cement delivery means as, for example, taught by the Preissman reference for the cement delivery means in the Bhatnagar et al. kit wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these devices would work equally well in the claimed device.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,395,007) in view of Hawkins et al. (US 5,638,997).



Bhatnagar et al. disclose a kit having a cement delivery means 42, a tubing assembly 44 removably attached to the cement delivery means 42, a cannula 12, a stylet 2, a hammer and a forceps (Fig. 4, col. 5, lines 31-66, col. 6, lines 1-35, col. 8, lines 45-59, col. 9, lines 46-67, col. 10, lines 1-26 and lines 55-61).

Bhatnagar et al. further disclose that any cement delivery means could be used (col. 9, lines 7-17).

Bhatnagar et al. disclose all elements of the claimed invention except for a cement delivery means including a plunger assembly and a dispenser hub assembly disposed around the shaft.

Hawkins et al. teach a cement delivery means having a tube 24 filled with bone cement removably attached to a cement injector gun wherein the gun has a plunger assembly, the plunger assembly having a handle 4 and a shaft 1 and a dispenser hub assembly around the plunger assembly (Fig. 1, col. 2, lines 64-67 and col. 3, lines 1-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made have substituted a cement delivery means as, for example, taught by the Hawkins et al. reference for the cement delivery means in the Bhatnagar et al. kit wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these devices would work equally well in the claimed device.

Claims 21 and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US 5,156,606) in view of Hawkins et al. (US 5,638,997).

Chin discloses a kit including a cement delivery means and a slap hammer 22 (Fig. 1 and col. 3, lines 34-52).

Chin discloses all elements of the claimed invention except for the cement delivery means having a tube with bone cement removably attached to a dispenser hub assembly when the shaft is attached to the dispenser hub assembly.

Hawkins et al. teach a cement delivery means having a tube 24 filled with bone cement removably attached to a cement injector gun wherein the gun has a plunger

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assembly, the plunger assembly having a handle 4 and a shaft 1 and a dispenser hub assembly around the plunger assembly (Fig. 1, col. 2, lines 64-67 and col. 3, lines 1-47).

It would have been obvious to one of ordinary skill in the art to substitute a cement delivery means as, for example, taught by the Hawkins et al. reference for the cement delivery means of the Chin kit wherein so doing would amount to mere substitution of one functionally equivalent cement delivery means for another within the same art and the selection of any of these devices would work equally well in the Chin kit.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US 5,156,606) and Hawkins et al. (US 5,638,997) further in view of Preissman (US 6,383,190).

The combination of Chin and Hawkins et al. discloses all elements of the claimed invention except for a tubing assembly, a luer fitting, a cannula and a stylet for insertion into the cannula.

Preissman teaches providing a tubing assembly including: a tubing assembly 11, luer fitting 52, a stylet 2 and a cannula 10 for delivery of implant material at a site (col. 8, lines 20-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a tubing assembly, luer fittings, stylet and cannula, as taught by Preissman, in the kit of the combination of Chin and Hawkins et al., as taught by Preissman, for the purpose of delivery of implant material to a specific site.

### ***Response to Arguments***

Applicants' arguments submitted under "REMARKS" in the response filed on May 16, 2006 have been fully considered but are moot in view of the new grounds of rejection.

### ***Allowable Subject Matter***

Claims 6-9 and 17-19 are allowed.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

*Anuadha Ramana*  
June 26, 2006